

SETTLEMENT AGREEMENT

FOR SETTLEMENT PURPOSES ONLY

I. PARTIES

This Settlement Agreement ("Agreement") is entered into this 20th day of March, 2003. The parties to this Agreement are the State of Michigan and LifeScan, Inc. and Johnson & Johnson, Co. (collectively "LifeScan") and are collectively referred to as the "Parties."

The Parties now agree as follows:

II. PREAMBLE

A. LifeScan, a California corporation, headquartered in Milpitas, California, is a wholly owned subsidiary of Johnson & Johnson, Co., a New Jersey corporation headquartered in New Brunswick, New Jersey. LifeScan develops, designs, manufactures, distributes and sells medical devices called blood glucose monitoring systems, which included a blood glucose meter and related products such as a lancet and chemically treated white melenix test strips.

B. LifeScan has entered into a Settlement Agreement with the United States of America, acting through its Department of Justice (the "Department of Justice"), the Office of the Inspector General ("OIG-HHS") of the United States Department of Health and Human Services, and the Department of Defense (the "Department of Defense") (collectively the "United States") and relators Robert Konrad and John Pumphrey (collectively the "Relators"), and is entering into settlement agreements with the states as set forth in Exhibit "A" ("the Participating States"). Collectively, this Agreement and the agreements referred to in this paragraph address the United States' and the Participating States' civil or administrative claims against the Defendants involving the introducing and delivering into interstate commerce between July 1, 1996 and June 30, 1998 an adulterated and misbranded medical device, namely the SureStep blood glucose monitoring system.

C. The State of Michigan contends that it sustained damages between July 1, 1996 and June 30, 1998 resulting from LifeScan introducing and delivering into interstate commerce an adulterated and misbranded medical device, namely the SureStep blood glucose monitoring system, for which the participating states' respective Medicaid programs subsequently were caused to pay. The conduct specified above in this paragraph is hereinafter referred to as the "Covered Conduct."

D. LifeScan, denies the allegations set forth in paragraph B and C above, and denies that it is liable under the False Claims Act, 31 U. S. C. Sections 3729-3733, or any other civil or administrative cause of action relating to the introduction and delivering into interstate commerce of an adulterated and misbranded medical device, for which federal and state health care programs subsequently were caused to pay.

E. In order to avoid the disruption, delay, uncertainty, inconvenience, and expense of protracted litigation of these claims, the Parties have agreed to a full and final settlement as set forth below.

III. TERMS and CONDITIONS

NOW, THEREFORE, in consideration of the mutual promises, covenants, and obligations set forth below, and for good and valuable consideration as stated herein, the Parties agree as follows:

OBLIGATIONS OF LIFESCAN

1. Payment to the Participating States: LifeScan agrees to pay the Participating States \$2,575,926.65, which includes all claims for interest (the "Settlement Amount"), within seven (7) days following the final execution of this Agreement by all Parties. The United States and the Participating States, will determine the distribution of the Settlement Amount to the United States, the Participating States, and other parties.

2. Manner and Method of Payment: The payment provided for in paragraph 1 shall be by release of \$2,575,926.65 currently held on deposit in an escrow account at HRBC, New York

City, New York. These funds were received from the United States government as a result of payments made by LifeScan pursuant to the earlier federal settlement in this matter.

3. Integrity Agreement: LifeScan has entered into a Corporate Integrity Agreement ("CIA") with the OIG-HHS. That CIA is incorporated into this Agreement by reference. LifeScan will, consistent with the terms of the CIA, upon execution of the CIA, implement its obligations thereunder. The State of Michigan shall be entitled to request and review all reports, and have access to all information that LifeScan is required to report, produce or maintain pursuant to the CIA, either through HHS-OIG or directly from LifeScan.

OBLIGATIONS OF THE STATE OF MICHIGAN

4. The total Settlement Amount for the State of Michigan, representing both the state and federal share of claims settled for the State's Medicaid program, is \$54,388 88. The amount which has been paid to the federal government pursuant to its agreement with LifeScan is \$26,632.68 to settle that portion of the State of Michigan's Medicaid claims which were federally funded. The amount which shall be paid to the State of Michigan to settle that portion of the Medicaid claims which is state-funded is \$27,756.20.

5. Dismissal and Release: In consideration of this Agreement and payment set forth herein and subject to the exceptions from release (paragraph 7), the State of Michigan shall release and forever discharge LifeScan, Johnson & Johnson, Co., and each and any of their divisions, parents, subsidiaries, predecessors, successors, assignees, transferees, and each of their current or former directors, officers, and employees from any civil or administrative claims for damages or penalties that the State of Michigan has or may have for causing the submission of claims to the State Medicaid Program for the Covered Conduct.

6. In consideration of the obligations of LifeScan set forth in this Agreement, conditioned upon LifeScan's payment in full of the Settlement Amount, and subject to paragraph 7 below, the State of Michigan agrees to release and refrain from directing or maintaining any administrative claim or any action seeking exclusion from the State of Michigan's Medicaid program against LifeScan, Johnson & Johnson, Co., and each and any of their divisions, parents, subsidiaries, predecessors, successors, assignees, transferees, and each of their current or former directors, officers and employees for the Covered Conduct, except as reserved in paragraph 7

below, and as reserved in this paragraph. Nothing in this Agreement precludes the State of Michigan from taking action against LifeScan in the event that LifeScan is excluded by the federal government, or for conduct and practices other than the Covered Conduct. LifeScan acknowledges that the State of Michigan does not have the authority to release LifeScan from any claims or actions which may be asserted by private payors or insurers, including those that are paid on a capitated basis for providing health care to the State's Medicaid recipients.

7. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including LifeScan) are any and all of the following:

- i. Any criminal liability that LifeScan has or may have to the State of Michigan;
- ii. Any civil or administrative liability that LifeScan has or may have under any state statute, regulation or rule not covered by the release in paragraph 5 and paragraph 6 above.
- iii. Any claims based upon such obligations as are created by this Agreement.

MISCELLANEOUS PROVISIONS

8. LifeScan releases the State of Michigan, and its agencies, employees, servants and agents from any claim, including attorneys' fees, costs and expenses of every kind and however denominated, which LifeScan has asserted, could have asserted, or may assert in the future against the State of Michigan, and its agencies, employees, servants and agents, related to the Covered Conduct alleged in paragraph B, and the State of Michigan's investigation and prosecution thereof. LifeScan waives and will not assert any defenses LifeScan may have to any criminal prosecution or administrative action relating to the Covered Conduct, which defenses may be based, in whole or in part, on the Double Jeopardy or Excessive Fines Clauses of the Constitution or principles set forth in Hudson v. United States, 118 S. Ct. 488 (1997), and Austin v. United States, 509 U.S. 602 (1993). LifeScan, the United States and the State of Michigan agree that the amount that LifeScan has agreed to pay under the terms of this Agreement is not punitive in effect or nature for purposes of such criminal prosecution or administrative action. Nothing in this paragraph or any provision of this Agreement constitutes a characterization of the

Settlement Amount for purposes of the Internal Revenue Code or the tax code of the State of Michigan.

9. The amount that LifeScan must pay pursuant to this Agreement pursuant to paragraph 2 above will not be decreased as a result of the denial of claims for payment now being withheld from payment by the State of Michigan's Medicaid program related to the Covered Conduct, and LifeScan agrees not to resubmit to the State of Michigan's Medicaid program any previously denied claims related to the Covered Conduct, and agrees not to appeal any such denials of claims.

10. Unallowable Costs: LifeScan agrees that all costs (as defined in Federal Acquisition Regulations ("FAR") 31.205-47 and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. 1395-1395ddd (1997) and 1396-1396v (1997), and the regulations promulgated thereunder) incurred by or on behalf of LifeScan, in connection with:

- i. The matters covered by this Agreement;
- ii. The United States or the Participating States' investigation of the matters covered by this Agreement;
- iii. LifeScan's investigation, defense, and corrective actions undertaken in response to the United States' or the Participating States' investigation in connection with the matters covered by this Agreement (including attorney's fees and the obligations undertaken pursuant to the CIA incorporated in this Settlement Agreement);
- iv. The negotiation of this Agreement; and
- v. The payment made pursuant to this Agreement,

are unallowable costs on Government contracts and under the Medicare Program, Medicaid Program, TRICARE, Veteran Affairs Program ("VA"), and FEHBP (hereinafter, "unallowable costs").

11. LifeScan will not charge such unallowable costs directly or indirectly to any contracts with the United States or any of the Participating States' Medicaid programs, or seek payment for such unallowable costs through any cost report, cost statement, information statement or payment request submitted by LifeScan, Johnson & Johnson, Co., or any of their subsidiaries to the Medicare, Medicaid, TRICARE, VA or FEHBP programs.

12. This Agreement is intended to be for the benefit of the Parties only, and by this instrument the Parties do not release any claims against any other person or entity except those identified in paragraphs 5 and 6.
13. LifeScan agrees that it will not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents or sponsors based upon the claims for payment covered by the Agreement. LifeScan waives any causes of action against these beneficiaries or their parents or sponsors based upon the claims for payment covered by this Agreement.
14. Negotiating Team Expenses In addition to all other payment and responsibilities under this Agreement, LifeScan agrees to pay all reasonable travel costs and expenses of the state negotiating team, which is \$1,500.00. LifeScan will pay this amount by separate check or wire transfer made payable to the National Association of Medicaid Fraud Control Units at the same time as payment made pursuant to paragraph 1 above.
15. This Agreement is governed by the laws of the State of Michigan.
16. This Agreement and the CIA that is incorporated herein by reference constitute the complete agreement between the State of Michigan and LifeScan. This Agreement may not be amended except by written consent of the Parties, except that only LifeScan and OIG-HHS must agree in writing to modification of the Corporate Integrity Agreement.
17. The undersigned individuals signing this Agreement represent and warrant that they are authorized to execute this Agreement.
18. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.
19. The Parties agree that they will execute and deliver all such other documents and instruments as may be necessary and appropriate to effectuate the terms of this Agreement.
20. This Agreement is effective on the date of signature of the last signatory to the Agreement, and is binding on successors, transferees, heirs, and assigns.

FOR THE STATE OF MICHIGAN
ATTORNEY GENERAL

FOR LIFESCAN, INC.

By: David L. Edick for

Wallace T. Hart
MEDICAID FRAUD CONTROL UNIT
DIRECTOR

Date: 7/25/02

For the Medicaid Program of the State of Michigan

By: Carol Grace

Date: 7/30/02

By: P. J. [Signature]

Title: President

Date: 3-20-03